

Claims

1. A transdermal therapeutic system (TTS) for continuous administration of pramipexol, comprising a backing layer and at least one active ingredient-containing polymer layer which comprises the active ingredient pramipexol, wherein the active ingredient-containing polymer layer comprises at least one pressure-sensitive adhesive polymer from the group of silicones (polydimethylsiloxanes), of polyisobutylenes, of polybutenes, of styrene-isoprene-styrene block copolymers in combination with resins, and of carboxyl group-free polyacrylates.
- 15 2. The TTS as claimed in claim 1, which comprises a further pressure-sensitive adhesive layer, an additional membrane which controls the rate of release of pramipexol, an additional active ingredient-containing layer or an additional supporting layer.
- 20 3. The TTS as claimed in claim 1 or 2, wherein the pressure-sensitive adhesive polymer is a carboxyl group-free polyacrylate which can be prepared by polymerization of a monomer mixture of at least one acrylic ester or methacrylic ester.
- 25 4. The TTS as claimed in claim 3, wherein the monomer mixture comprises at least one acrylic ester or methacrylic ester with linear, branched or cyclic aliphatic C₁-C₁₂ substituents without other functional groups.
- 30 35 5. The TTS as claimed in claim 3 or 4, wherein the monomer mixture additionally comprises at least

one hydroxyl group-containing acrylic ester or one hydroxyl group-containing methacrylic ester in a proportion by weight of less than 10 %.

5 6. The TTS as claimed in one or more of claims 3 to 5, wherein the monomer mixture additionally comprises vinyl acetate in a proportion by weight of less than 50 %, preferably less than 25 % and particularly preferably between 0 and 5 %.

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7. The TTS as claimed in one or more of the preceding claims, wherein the active ingredient pramipexol is present in the active ingredient-containing polymer layer in dissolved, emulsified and/or dispersed form.

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8. The TTS as claimed in one or more of the preceding claims, wherein the active ingredient pramipexol is present as *S*-(*-*) enantiomer, *R*-(*+*) enantiomer or racemic mixture of these two enantiomers in the active ingredient-containing polymer layer.

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9. The TTS as claimed in one or more of the preceding claims, wherein the active ingredient pramipexol is present as free base, as hydrate, solvate and/or pharmaceutically acceptable salt in the active ingredient-containing polymer layer.

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10. The TTS as claimed in one or more of the preceding claims, wherein the active ingredient pramipexol is present as *S*-(*-*) enantiomer in the form of the free base in the active ingredient-containing polymer layer.

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35 11. The TTS as claimed in one or more of the preceding claims, which is able to deliver the active

ingredient pramipexol continuously to a patient's skin over a period of from 4 to 7 days.

12. The TTS as claimed in one or more of the preceding
5 claims, which is able to release the active
ingredient pramipexol with a flux rate greater
than $5 \mu\text{g}/\text{cm}^2 \text{ h}$ over the period between 24 hours
after administration to 168 h after
administration.
- 10 13. The TTS as claimed in one or more of the preceding
claims, which is able to release the active
ingredient pramipexol with a flux rate greater
than $5 \mu\text{g}/\text{cm}^2 \text{ h}$ over the period between 24 hours
15 after administration to 72 h after administration.
14. The TTS as claimed in one or more of the preceding
claims, wherein the active ingredient pramipexol
is present therein in a proportion of less than
20 75 % by weight, preferably between 2 and 40 % by
weight and particularly preferably between 10 and
25 % by weight.
15. The TTS as claimed in one or more of the preceding
25 claims, wherein the daily delivery rate of
pramipexol is between 0.1-10 mg, preferably
between 0.5-4.5 mg.
16. The TTS as claimed in one or more of the preceding
30 claims, wherein the active ingredient-containing
polymer layer comprises the active ingredient
pramipexol in a concentration below the saturation
solubility.
- 35 17. The TTS as claimed in one or more of the preceding
claims, which comprises between 5-40 % by weight,

preferably between 10-20 % by weight of butane-diol, 1,2-propanediol, propylene glycol and/or lauryl lactate.

- 5 18. The TTS as claimed in one or more of the preceding
claims, which comprises up to 1 % of antioxidants
and/or stabilizers.
- 10 19. The TTS as claimed in one or more of the preceding
claims, which is employed for the therapeutic
treatment of a patient's pathological condition
where administration of pramipexol contributes to
alleviating the symptoms and/or restoring physical
capacity.
- 15 20. The TTS as claimed in claim 19, wherein the
patient's pathological condition is caused by
depression, tremor, ADHD (attention deficit hyper-
activity disorder), anhedonia, HIV dementia, drug
dependency, schizophrenia, ALS (amyotrophic
lateral sclerosis), adiposity, obesity and/or
diabetes.
- 25 21. The TTS as claimed in claim 19, wherein the
patient's pathological condition can be treated on
the basis of the neuroprotective effect and/or of
the anticonvulsant effect of pramipexol.
- 30 22. The TTS as claimed in claim 19, wherein the
pathological condition is restless leg syndrome
and/or Parkinson's disease.
- 35 23. The use of pramipexol for producing a self-
adhesive transdermal therapeutic system for the
therapeutic treatment of a patient's pathological
condition where administration of pramipexol

contributes to alleviating the symptoms and/or restoring physical capacity.

24. The use as claimed in claim 23, wherein the patient's pathological condition is caused by depression, tremor, ADHD (attention deficit hyperactivity disorder), anhedonia, HIV dementia, drug dependency, schizophrenia, ALS (amyotrophic lateral sclerosis), adiposity, obesity and/or diabetes.
25. The use as claimed in claim 23, wherein the patient's pathological condition can be treated on the basis of the neuroprotective effect and/or of the anticonvulsant effect of pramipexol.
26. The use as claimed in claim 23, wherein the pathological condition is restless leg syndrome and/or Parkinson's disease.
27. A method for the treatment for the therapeutic treatment of a patient's pathological condition where administration of pramipexol contributes to alleviating the symptoms and/or restoring physical capacity, comprising the steps:
 - a) attachment of a transdermal therapeutic system (TTS) which comprises a backing layer and at least one active ingredient-containing polymer layer with the active ingredient pramipexol to an uninjured site on a patient's skin, and
 - b) continuous administration of the active ingredient pramipexol to the patient's skin over a prolonged period,

comprises at least one pressure-sensitive adhesive polymer from the group of silicones (polydimethylsiloxanes), of polyisobutylenes, of polybutenes, of styrene-isoprene-styrene block copolymers in combination with resins, and of carboxyl group-free polyacrylates.

10 28. The method as claimed in claim 27, wherein the patient's pathological condition is caused by depression, tremor, ADHD (attention deficit hyperactivity disorder), anhedonia, HIV dementia, drug dependency, schizophrenia, ALS (amyotrophic lateral sclerosis), adiposity, obesity and/or diabetes.

15 29. The method as claimed in claim 27, wherein the patient's pathological condition can be treated on the basis of the neuroprotective effect and/or of the anticonvulsant effect of pramipexol.

20 30. The method as claimed in claim 27, wherein the pathological condition is restless leg syndrome and/or Parkinson's disease.